

**REMARKS**

Claims 15, 17-32 and 36 are all the claims pending in the application; claims 15, 17, 21, 23-32 and 36 are rejected; claims 18-20 and 22 are objected to.

After entry of the amendment, claims 1-36 will be cancelled, and new claims 37-74 will be pending.

New claims 37-41 correspond to claims 18-22, wherein claims 18-22 have been placed in independent form and have incorporated the subject matter of the claim (claim 15) from which cancelled claims 37-41 depended.

The five new groups of claims, namely, new claims 42, 43-50, 51-58, 59-66, and 67-74 each correspond to dependent claims 23-29 and 32 that were pending prior to the instant amendment.

Recitation of non-immune related cerebrovascular disease in claim 40 is supported in the specification at page 2, lines 14-17.

No new matter has been added. Entry of the Amendment is respectfully requested.

**I. Claim Objections**

At paragraph 3 of the Office Action, the Examiner notes that claims 18-20 and 22 are objected to as being dependent upon a rejected base claim, but that there are no outstanding rejections of these claims.

As these claims are thus allowable, except for their dependency on rejected base claims, Applicants include herewith amendments to these claims (along with claim 21) to convert them into independent claims, based on claim 15 from which each of the claims depended. New claims 37-41 correspond to claims 18-22.

Applicants also include new claims 42-74. These claims comprise five sets of claims, where each set depends from one of new independent claims 37-41. Each of the five sets of claims correspond to cancelled claims 23-29 and 32.

New claims 37-39 and 41

As new independent claims 37-39 and 41 correspond to the allowable subject matter of claims 18-20 and 22, Applicants respectfully request allowance of these claims, and of claims 42, 43-50, 51-58, and 67-74 that depend therefrom.

New claim 40

As to new independent claim 40 (corresponding to cancelled claim 21), and claims 59-66 dependent therefrom, Applicants have the following comments.

Applicants note that new claim 40 describes a method of diagnosing cardiovascular disease, atherosclerosis or a non-immune related cerebrovascular disease, by identifying the NA2/NA2 genotype for the FcγRIIIB receptor in a human. Thus, claim 40 largely parallels claim 21 that has now been cancelled.

With regard to claim 21, the Examiner has cited Kimberly et al. (WO 96/06952), in view of Bux et al. (*Blood*, 1997), against this claim. The Examiner has stated that Kimberly et al. discloses methods of diagnosing “predisposition to severe forms of autoimmune diseases” by determining patterns of Fcγ receptor alleles. The Examiner notes that predisposition to Wegener’s granulomatosis (“WG”) is determined by identifying a patient’s pattern of Fcγ RIIIB alleles, and that the NA1/NA1 genotype is more prevalent in WG patients than the normal population. The Examiner acknowledges that Kimberly et al. does not teach the detection of the NA2/NA2 genotype in the method of disclosed therein.

The Examiner states that Bux et al. discloses that the NA2/NA2 genotype is associated with neutropenia in some individuals, that neutropenia may trigger cerebral hemorrhage, which is a type of cerebrovascular disease. The Examiner also states that Bux et al. discloses that neutropenia can cause meningitis, itself a disorder of which one well known complication is cerebral hemorrhage.

The Examiner concludes that it would have been obvious to have modified the method of Kimberly et al to detect the presence of the NA2/NA2 genotype as an indicator of a “non-benign” prognosis of increased risk for neutropenia (cerebrovascular disease).

In response to the Examiner’s position, Applicants note that new claim 40 recites non-immune related cerebrovascular disease. In contrast, the method of Kimberly et al. only pertains to the diagnosis of a predisposition to autoimmune diseases, such as WG (see *Summary*, page 4 of Kimberly et al.). Thus, Kimberly et al. does not teach or suggest a method for diagnosing a predisposition to the development of a non-immune related cerebrovascular disease as recited in claim 40. Nor, as noted above, does Kimberly teach or suggest a method for diagnosing a predisposition to such a disease by detecting the NA2/NA2 genotype.

Bux et al. does not cure the defects in the disclosure of Kimberly et al. Bux et al. discloses the results of studies on the involvement of Fcγ RIIIB in alloimmune neonatal neutropenia. Thus, the disease (condition) of Bux et al. is an alloimmune disease which is not one of the diseases recited in claim 40. Bux et al. does not teach or suggest determining the genotype of Fcγ RIIIB in order to make a prognosis concerning a non-immune related cerebrovascular disease as recited in claim 40.

Thus, neither Kimberly et al. or Bux et al., alone or in combination, teach or suggest a relationship between any of the diseases recited in claim 40, and a determination of the NA2/NA2 genotype for Fcγ RIIIB. The form of cerebrovascular disease disclosed in Bax et al. is the result of an aberrant immune system. In contrast, the cerebrovascular disease recited in claim 40 is not immune system-based. The skilled artisan would not expect that a genetic alteration in a particular receptor that results in an autoimmune disease would also lead to a completely separate, non-immune system related disease.

In view of these comments, Applicants assert that new claim 40, and the claims dependent therefrom, are not taught or suggested by Kimberly et al. or Bux et al., either alone or in combination. Applicants therefore respectfully request allowance of these claims.

## **II. Rejection of Claims Under 35 U.S.C. §112**

In paragraph 6, on page 3 of the Office Action, the Examiner rejects claims 15, 17, 23-32 and 36 under 35 U.S.C. §112, first paragraph for the reasons of record.

In response, Applicants include herewith an amendment canceling each of the rejected claims, thus making this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

## **III. Rejection of Claims Under 35 U.S.C. §102**

In paragraph 8, on page 5 of the Office Action, the Examiner rejects claims 15, 17, 23, 26-27, 30-32 and 36 under 35 U.S.C. §102(b) as being anticipated by Kimberly et al. for the reasons of record.

In response, Applicants include herewith an amendment canceling each of the rejected claims, thus making this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**IV. Rejection of Claims Under 35 U.S.C. §103**

**A.** In paragraph 9, on page 7 of the Office Action, the Examiner rejects Claims 25 and 29 under 35 U.S.C. §103 as being unpatentable over Kimberly et al in view of Herridge et al for the reasons of record.

In response, Applicants include herewith an amendment canceling each of the rejected claims, thus making this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**B.** In paragraph 10, on page 8 of the Office Action, the Examiner rejects Claim 21 under 35 U.S.C. §103 as being unpatentable over Kimberly et al in view of Bux et al for the reasons of record.

In response, Applicants include herewith an amendment canceling claim 21, thus making this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants refer to their comments above regarding the allowability of new claim 40.

**C.** In paragraph 11, on page 10 of the Office Action, the Examiner rejects Claims 24 and 28 under 35 U.S.C. §103 as being unpatentable over Kimberly et al in view of Bux et al and in further view of Von Nostrand et al.

In response, Applicants include herewith an amendment canceling each of the rejected claims, thus making this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**V. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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**23373**

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